

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
WACO DIVISION**

CANOPY GROWTH CORPORATION,

Plaintiff,

v.

GW PHARMA LIMITED and
GW RESEARCH LIMITED,

Defendants.

Civil Action No. 6:20-cv-01180-ADA

JURY TRIAL DEMANDED

DEFENDANTS' OPENING CLAIM CONSTRUCTION BRIEF

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I. INTRODUCTION

Defendants GW Pharma Limited (“GWP”) and GW Research Limited (“GWR”) (collectively, “Defendants”) respectfully submit their Opening Claim Construction Brief in support of their proposed construction for U.S. Patent No. 10,870,632 (Ex. 1, “the ’632 Patent”).¹ Plaintiff Canopy Growth Corporation (“Canopy” or “Plaintiff”) has alleged that GWP’s process for manufacturing cannabidiol (“CBD”), the active ingredient in EPIDIOLEX®, infringes claims of the ’632 patent. EPIDIOLEX® is approved by the U.S. Food and Drug Administration (“FDA”) for treatment of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex in patients 1 year of age and older. It is the first and currently only FDA-approved drug containing CBD.

The parties dispute construction of the term “CO₂ [carbon dioxide] in liquefied form under subcritical pressure and temperature conditions,” which is recited in the two independent claims of the ’632 patent. In its May 11, 2021 infringement contentions, Canopy relied on extraction processes described in two GWP patents to argue that GWP’s CBD manufacturing process met this limitation. Having subsequently learned, through review of confidential documents produced in this litigation, that the patents on which it relied did not reflect the commercial manufacturing process for the CBD used in EPIDIOLEX®, Canopy now seeks to improperly broaden the scope of its claims through incorrect construction of the disputed term.

Canopy’s attempt to rewrite its claims must fail. As explained below, Defendants’ approach to claim construction follows the Federal Circuit’s guidance in *Phillips* that disputed claim terms should be construed from the perspective of a person of ordinary skill in the art (“POSA”) in view of the pertinent intrinsic evidence. Defendants’ proposed construction—that the

¹ “Ex. 1” *et seq.* refers to exhibits attached to the concurrently filed supporting declaration of Steven M. Zager.

contested claim language means “CO₂ in liquified form under both subcritical pressure and temperature conditions”—is supported by the language of the claims themselves, the specification, and the prosecution history.

Although Canopy purports to apply the “plain and ordinary meaning” of the disputed term, under Canopy’s interpretation, the disputed language would encompass the use of carbon dioxide (“CO₂”) under subcritical pressure *or* subcritical temperature. Canopy’s interpretation is inconsistent with the plain language of the claims and specification, and attempts to recapture claim scope that Applicants disclaimed during prosecution.

II. STATEMENT OF FACTS

A. Supercritical and Subcritical CO₂

CO₂ is commonly understood to exist as a solid, liquid, or gas. However, above a certain pressure and temperature, known as the “critical point,” matter exists as a “supercritical fluid” in which it has characteristics of both a liquid and a gas. (*See* Ex. 2, GW PHARMA_0003566 at 3566; Ex. 3, Canopy_000001121 at 1121.) The critical pressure and temperature for CO₂ are 73.8 bar (72.8 atm) and 31°C, respectively. (Ex. 2 at GW PHARMA_0003566; Ex. 3 at Canopy_000001124.) CO₂ has been used for decades as a solvent in extraction processes for organic material in (1) the supercritical state, or (2) as a liquid under either (a) subcritical temperature and supercritical pressure or (b) subcritical pressure and subcritical temperature. (*See, e.g.*, Ex. 2 at GW PHARMA_0003566.) At supercritical temperature and subcritical pressure, CO₂ is a gas and it is typically not used for extraction in that state. (*See* Ex. 2 at GW PHARMA_0003566; Ex. 3 at Canopy_000001121; *see also* Ex. 4, excerpts from the prosecution history for U.S. Patent No. 8,895,078 (“the ’078 patent”) at 15 (1/3/2009 Remarks at 7) (“[I]t is not possible to extract plant material using solid or gaseous CO₂.”).)

B. The '632 Patent

The '632 patent generally relates to methods “for producing an extract from *cannabis* plant matter, containing tetrahydrocannabinol, cannabidiol and optionally the carboxylic acids thereof,” using CO₂ as a solvent. (See Ex. 1 at Abstract.) The specification of the '632 patent states that, according to the alleged invention,

[P]lant material is extracted with the aid of CO₂ under [1] supercritical pressure and temperature conditions at a temperature in the range of approx. 31° C. to 80° C. and at a pressure in the range of approx. 75 bar to 500 bar, or [2] in the subcritical [sic] range at a temperature of approx. 20° C. to 30° C. and a supercritical pressure of approx. 100 bar to 350 bar; or [3] ***extracted under subcritical [sic] pressure and temperature conditions*** and the obtained primary extract is separated under subcritical [sic] conditions, or under conditions that are subcritical [sic] in terms of pressure and supercritical in terms of temperature.

(Ex. 1 at 5:10-20.)² As highlighted above and discussed further below, the '632 patent thus identifies the use of CO₂ “under subcritical [sic] pressure and temperature” as one of three alternative processes for the initial extraction of plant material according to the claimed invention.

The '632 patent has two independent claims, claims 1 and 14. Claims 1 and 14 recite as follows:

1. A process for producing an extract containing Tetrahydrocannabinol (THC) and/or cannabidiol (CBD), and optionally the carboxylic acids thereof, from a *cannabis* plant material or a primary extract thereof, said process comprising:

- (1) subjecting the *cannabis* plant material or primary extract thereof to ***CO₂ in liquefied form under subcritical pressure and temperature conditions*** to extract cannabinoid components; and
- (2) reducing the pressure and/or temperature to separate tetrahydrocannabinol and/or cannabidiol, and optionally the carboxylic acids thereof, from the CO₂.

14. A process for producing an extract containing Tetrahydrocannabinol (THC) and/or cannabidiol (CBD) from a *cannabis* plant material or a primary extract thereof, said process comprising:

- (1) decarboxylating cannabinoid carboxylic acids in the *cannabis* plant material or primary extract thereof;

² Unless otherwise noted, all emphasis is added, and all internal citations and internal quotation marks are omitted.

- (2) subjecting the decarboxylated *cannabis* plant material or primary extract thereof to ***CO₂ in liquefied form under subcritical pressure and temperature conditions*** to extract cannabinoid components; and
- (3) reducing the pressure and/or temperature to separate tetrahydrocannabinol and/or cannabidiol from the CO₂.

(Ex. 1 at claims 1 and 14 (“cannabis” italicized in original).)

III. ARGUMENT

A. Legal Standard

A patent’s claim terms are not to be construed in the abstract, but rather, in the context in which they were presented and used by the patentee, as would have been understood by a POSA in view of the intrinsic record. *Biogen Idec, Inc. v. GlaxoSmithKline LLC*, 713 F.3d 1090, 1094 (Fed. Cir. 2013) (“[A] term’s ordinary meaning must be considered in the context of all the intrinsic evidence, including the claims, specification, and prosecution history.”). The patent specification is “the single best guide to the meaning of a disputed term.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) (*en banc*).

Like the patent’s specification, a patent’s prosecution history also “can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution” *Id.* at 1317; *see also Vitronics Corp. v. Conceptiontronic, Inc.*, 90 F.3d 1576, 1582-83 (Fed. Cir. 1996). Any explanation, elaboration, or qualification presented by the inventor during patent examination is relevant, for it is black letter law that patent claims “may not be construed one way in order to obtain their allowance and in a different way against accused infringers.” *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995); *see also Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 653 F.3d 1296, 1305 (Fed. Cir. 2011) (the role of claim construction is to “capture the scope of the actual invention” that is disclosed, described, and patented).

A court, in its discretion, may consider extrinsic evidence. *See Phillips*, 415 F.3d at 1319. But “while extrinsic evidence ‘can shed useful light on the relevant art,’ ... it is ‘less significant than the intrinsic record in determining ‘the legally operative meaning of claim language.’” *Id.* at 1317 (citing *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004), *quoting Vanderlande Indus. Nederland BV v. Int’l Trade Comm’n*, 66 F.3d 1311, 1318 (Fed. Cir. 2004)). “[E]xtrinsic evidence in general [is] ... less reliable than the patent and its prosecution history in determining how to read claim terms” and courts are cautioned to discount any extrinsic evidence that contradicts the intrinsic evidence. *Id.* at 1318.

Prosecution disclaimer “precludes patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution.” *Aylus Networks, Inc. v. Apple Inc.*, 856 F.3d 1353, 1359 (Fed. Cir. 2017). When “the alleged disavowing actions or statements made during prosecution [are] ... both clear and unmistakable,” prosecution disclaimer applies. *Id.* “Thus, when the patentee unequivocally and unambiguously disavows a certain meaning to obtain a patent, the doctrine of prosecution history disclaimer narrows the meaning of the claim consistent with the scope of the claim surrendered.” *Biogen*, 713 F.3d at 1095. This doctrine “promotes the public notice function of the intrinsic evidence and protects the public’s reliance on definitive statements made during prosecution.” *Id.* The disclaimer can occur through amendment or argument. *Aylus Networks*, 856 F.3d at 1359.

B. Construction of the Disputed Claim Term

Canopy currently asserts claims 1-3, 5-16, and 18-25 of the ’632 patent. The parties dispute construction of the term “CO₂ in liquefied form under subcritical pressure and temperature conditions,” which appears in claims 1 and 14. The parties’ proposed constructions are as follows:

Term	Plaintiff's Proposed Construction	Defendants' Proposed Construction
CO ₂ in liquefied form under subcritical pressure and temperature conditions	Plain and ordinary meaning	CO ₂ in liquified form under both subcritical pressure and temperature conditions

At a meet and confer on July 29, 2021, the parties discussed their proposed constructions. Canopy indicated that under its proposed construction, the CO₂ need not be under both subcritical pressure and subcritical temperature to fall within the scope of the disputed term.³ Canopy's stated intention is therefore to apply a much broader construction of the disputed term than its "plain and ordinary meaning" would support.

1. The Claim Language Itself Supports Defendants' Construction

The claim construction analysis "must begin and remain centered on the language of the claims themselves, for it is that language the patentee chose to use to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.'" *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001) (quoting 35 U.S.C. § 112). Here, the language of the claims themselves supports Defendants' construction.

Both claims 1 and 14 recite that the "CO₂ in liquified form" is under "subcritical pressure **and** temperature conditions." The dispute is whether this means that both pressure **and** temperature are subcritical. Canopy's construction errs because it ignores the plain language of the claims. Under Canopy's construction, the disputed term would encompass use of CO₂ at a temperature **or** a pressure below the critical point, but not necessarily both—thus ignoring the claims' use of the connector "and" as well as the plural term "conditions." *See, e.g., TIP Sys., LLC v. Phillips &*

³ The parties also discussed the term "sequiterpenes," recited in claims 8 and 21. Canopy had initially identified this term for construction. Following the July 29 meet and confer, the parties agreed the term "sequiterpenes" could be construed as "sesquiterpenes" to account for a spelling error in the claims.

Brooks/Gladwin, Inc., 529 F.3d 1364, 1376 (Fed. Cir. 2008) (affirming construction of term “said dial tone actuating switch electronically connected to said phone line and said electronic circuit” as requiring connection “to **both** the said phone line and said electronic circuit board” based on claim’s use of the conjunction “and”).

The language of the ’632 patent’s dependent claims is also consistent with Defendants’ construction. Claims 4-7 and 17-20 include specific temperature and/or pressure values. All of these recited values are below the critical temperature and critical pressure. None of the dependent claims recite the use of a combination of temperature and pressure conditions where one condition is below the critical point, but not the other.

2. The ’632 Patent’s Specification Supports Defendants’ Construction

“[C]laims must be read in view of the specification, of which they are a part.” *Phillips*, 415 F.3d at 1315. A patent’s specification “is always highly relevant to the claim construction analysis. Usually it is dispositive; it is the single best guide to the meaning of a disputed term.” *Id.*

The specification of the ’632 patent further supports Defendants’ construction. The ’632 patent explains that, “in accordance with the claimed invention,” “plant material is extracted with the aid of CO₂” under one of three alternative conditions:

- (1) “under supercritical pressure and temperature conditions at a temperature in the range of approx., 31° C. to 80° C. and at a pressure in the range of approx. 75 bar to 500 bar” – *i.e.*, under supercritical pressure and temperature;
- (2) “in the subcritical [sic] range at a temperature of approx. 20° C. to 30° C. and a supercritical pressure of approx. 100 bar to 350 bar” – *i.e.*, under subcritical temperature and supercritical pressure; and
- (3) “under subcritical [sic] pressure and temperature conditions” – *i.e.*, under both subcritical pressure and temperature conditions.

(*See* Ex. 1 at 5:10-20.)

Defendants’ construction, but not Canopy’s, is consistent with alternative (3) being a separate and distinct alternative to (2). Canopy’s interpretation of the disputed term would encompass the scenario presented in alternative (2), in which the CO₂ is used under subcritical temperature and supercritical pressure. Because extraction with CO₂ at subcritical temperature and supercritical pressure is presented as a separate and unclaimed alternative to use of CO₂ “under subcritical [sic] pressure and temperature,” the claims cannot be interpreted so broadly as to read out that distinction. *See TIP Sys.*, 529 F.3d at 1373 (“[T]o construe the claim term to encompass the alternative embodiment in this case would contradict the language of the claims . . . [R]ead in the context of the specification, the claims of the patent need not encompass all disclosed embodiments.”); *Roche Diagnostics GMBH v. Enzo Biochem, Inc.*, No. 04-4046, 2017 WL 6988709, at *7 (S.D.N.Y. Oct. 2, 2017) (rejecting broad construction where patentee “disclosed broadly in the specification, but claimed narrowly. To read ‘biotin’ as expansively as Enzo urges would alter the language of the claims, which the Court declines to do.”).

In addition, the ’632 patent specification uses variations of the “subcritical pressure and temperature” term only in connection with pressures and temperatures that are *both* below the critical point for CO₂—never one but not the other. Specifically, the ’632 patent states:

- “The obtained extract is separated out under pressure and temperature conditions subcritical [sic] for CO₂, preferably at approx. 55 bar and approx, 25° C” (Ex. 1 at 7:22-24);
- “[I]n the second and third separating vessels, where Δ⁸-THC and Δ⁹-THC are separated out, conditions subcritical [sic] for CO₂ in terms of pressure and temperature are to prevail, in the second separating vessel preferably 60 bar and 30° C., in the third separating vessel preferably 55 bar and 25° C.” (Ex. 1 at 7:51-57).

In these cases, the identified pressure and temperature are both below the critical pressure and temperature for CO₂ (73.8 bar, and 31°C, respectively). At no point does the ’632 patent use

the language “subcritical pressure and temperature” in connection with a temperature that is subcritical, but a pressure that is not subcritical, or vice versa.

3. The Prosecution History Supports Defendants’ Construction

Defendants’ construction is supported by the prosecution history of both the ’632 patent and the ’078 patent, from which the ’632 patent claims priority as a continuation. The prosecution history of the ’078 patent is properly considered part of the intrinsic record of its child patent and is consistent with Defendants’ construction. *See Advanceme, Inc. v. Rapidpay, LLC*, No. 6:05-cv-424, 2006 WL 3761975, at *4 (E.D. Tex. Dec. 21, 2006) (“[T]he prosecution history of a parent patent is part of the prosecution history of the child patent.”) (citing *Goldenberg v. Cytogen*, 373 F.3d 1158, 1167 (Fed. Cir. 2004)). The prosecution history of the ’632 patent is not only consistent with Defendants’ construction, but reflects a disclaimer by the Applicants of the claim scope Canopy now purports to capture.

a) Applicants Distinguished Use of CO₂ Under Subcritical Temperature and Supercritical Pressure During Prosecution

Consistent with Defendants’ construction and the ’632 patent specification, during prosecution of the ’078 patent, Applicants distinguished the use of CO₂ under “subcritical pressure and temperature” from the use of CO₂ under subcritical temperature and supercritical pressure.

Throughout prosecution of the ’078 patent, the claims recited alternative extraction conditions using CO₂: (1) “under supercritical pressure and temperature conditions at a temperature in a range of approx. 31° C to 80° C and at a pressure in a range of approx. 75 bar or 500 bar,” or (2) “in liquefied form in the subcritical range at a temperature of approx. 20° C. to 30° C. and a supercritical pressure of approx. 100 bar to 350 bar,” or (3) “in liquefied form under subcritical pressure and temperature conditions.” (*See, e.g.*, Ex. 4 at 10 (1/3/2009 Claims at 2).) This language was ultimately incorporated in the issued claims. (*See* Ex. 5, ’078 patent at claims 1-3.)

On January 3, 2009, to overcome an indefiniteness rejection under 35 U.S.C. § 112, Applicants explained that “extraction is only carried out with CO₂ in the liquid or supercritical fluid state” – not in the solid or gas states. (Ex. 4 at 17 (1/3/2009 Remarks at 9); *see also id.* at 15 (1/3/2009 Remarks at 2).) Referencing a phase diagram for CO₂, Applicants explained that CO₂ extraction can be carried out with CO₂ under (1) supercritical conditions (*i.e.*, temperature and pressure above the critical point), or (2) “with CO₂ in the subcritical temperature range and supercritical pressure”, or (3) “with CO₂ in the subcritical pressure and temperature conditions,” and that the extraction step recited in the claims could be performed with CO₂ under any of those three conditions. (*Id.* at 16-17 (1/3/2009 Remarks at 8-9).) Applicants thus identified “subcritical pressure and temperature conditions” as a separate and distinct alternative from CO₂ at subcritical temperature and supercritical pressure.

As indicated by the phase diagram for CO₂, liquid CO₂ exists only under conditions of (1) subcritical temperature and supercritical pressure, or (2) subcritical temperature and subcritical pressure. (*See id.* at 16 (1/3/2009 Remarks at 8).) Accordingly, Applicants’ remarks demonstrate their intent to identify and claim *in the ’078 patent* (but, as discussed below, *not the ’632 patent*) the three sets of conditions under which CO₂ can be used for extraction of organic material: (1) supercritical CO₂, (2) liquid CO₂ under subcritical temperature and supercritical pressure, and (3) liquid CO₂ under both subcritical temperature and subcritical pressure.

Thus, Applicants could have drafted the claims of the ’632 patent to clearly encompass the scope that Canopy now seeks to capture through claim construction. They clearly and repeatedly identified extraction “with CO₂ in the subcritical temperature range and supercritical pressure” as a potential embodiment in the ’632 patent’s specification and during prosecution of the parent application. But, as discussed below, Applicants narrowed their claims during prosecution of the

'632 patent to “subcritical pressure and temperature conditions” to avoid the prior art. Defendants’ proposed construction is consistent with this record; Canopy’s is not.

**b) Applicants Surrendered Broader
Claim Scope Through Narrowing Amendments**

The claims of the '632 patent were initially drafted to include the alternative extraction conditions recited in the specification and claimed in the '078 patent. For example, claim 1 of the original claim set submitted during prosecution of the '632 patent recited, in relevant part:

[E]xtracting said plant material by means of CO₂

(a) under supercritical pressure and temperature conditions at a temperature in a range of approx. 31 °C to 80°C and at a pressure in a range of approx. 75 bar or 500 bar; or

(b) in liquefied form in the subcritical range at a temperature of approx. 20°C to 30°C and a supercritical pressure of approx. 100 bar to 350 bar; or

(c) in liquefied form under subcritical pressure and temperature conditions

(Ex. 6, '632 patent prosecution history excerpts at 6 (5/13/2014 Claims at 24).)

Over the course of prosecution, and in response to obviousness rejections, Applicants narrowed their claims. On May 16, 2018, the Examiner raised an obviousness rejection over U.S. Patent No. 6,403,126 (“Webster”), U.S. Patent No. 6,365,416 (“Elsohly”), and U.S. Patent No. 6,319,524 (“Gregg”), citing Webster’s use of supercritical CO₂ for extraction. (*See, e.g.*, Ex. 6 at 12 (5/16/2018 Non-Final Rejection at 3) (describing § 103 rejection over “cited reference [that] expressly teaches the claimed invention’s supercritical pressure and temperature”).) In response, on November 16, 2018, Applicants submitted a claim set with alternative (a), reciting “supercritical pressure and temperature conditions,” deleted from all independent claims, and alternative (b), reciting subcritical temperature and supercritical pressure, deleted from two out of three independent claims. (Ex. 6 at 27-29 (11/16/2018 Claims at 2-4).) Applicants indicated in remarks that the claims had been amended “to require that the extraction is not under supercritical pressure and temperature.” (Ex. 6 at 22 (11/16/2018 Remarks at 7).)

On March 1, 2019, the Examiner rejected the pending claims over Webster, Elsohly, and Gregg again, stating that a POSA would understand that the temperature and pressure used in Webster could be adjusted to meet the claims. (Ex. 6 at 38-39 (3/1/2019 Rejection at 6-7).) In response, on June 27, 2019, Applicants amended the claims to remove alternative (b), reciting subcritical temperature and supercritical pressure, from the only independent claim where it remained. (Ex. 6 at 44 (6/27/2019 Claims at 2).) In remarks, Applicants argued a POSA would not understand the supercritical temperature and pressure conditions used in Webster could be lowered to subcritical, and therefore “reading Webster as a whole would require a supercritical CO₂ and would teach away from the applicant’s claimed invention.” (Ex. 6 at 53-54 (6/27/2019 Remarks at 11-12).)

Thus, to avoid the prior art, over the course of the ’632 patent’s prosecution Applicants narrowed their claims to specifically exclude the two additional alternatives claimed in the parent ’078 patent but not the ’632 patent—namely, extraction with CO₂ under supercritical conditions, and with CO₂ under subcritical temperature and supercritical pressure. In doing so, Applicants surrendered the scope covered by these alternatives. *See Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 33 (1966) (“[C]laims that have been narrowed in order to obtain the issuance of a patent by distinguishing the prior art cannot be sustained to cover that which was previously by limitation eliminated from the patent.”); *see also Sportstar Athletics, Inc. v. Wilson Sporting Goods Co.*, No. 15-1438, 2017 WL 393589, at *12 (S.D. Tex. Jan. 30, 2017) (rejecting broader construction of limitation narrowed during prosecution), *aff’d*, 737 F. App’x 1006 (Fed. Cir. 2018). To support its infringement contentions, Canopy’s proposed construction now purports to recapture the use of CO₂ under subcritical temperature and supercritical pressure for extraction,

which was expressly disclaimed during prosecution. Canopy's unduly broad construction is inconsistent with the prosecution history and should not be adopted.

IV. CONCLUSION

Having learned the confidential details of GWP's manufacturing process, Canopy now seeks to improperly broaden the scope of the '632 patent's claims through construction. But, as described above, Canopy's proposed construction ignores the intrinsic record. Defendants' proposed construction is consistent with the language of the claims, specification, and Applicants' arguments and amendments during prosecution of the '632 patent and its parent application. For the foregoing reasons, Defendants' construction should be adopted.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that counsel of record who are deemed to have consented to electronic service are being served today, August 9, 2021, with a copy of this document via the Court's CM/ECF system per Local Rule CV-5(b)(1).

/s/ Steven M. Zager

Steven M. Zager